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EXAMINER

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ART UNIT PAPER NUMBER

1636

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/536,736

Applicant(s)
Bastian et al.

Examiner
William Sandals

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1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 1, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above, claim(s) 6-8, 56, and 57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 24-30, 32-49, 51-55, and 58 is/are rejected.
- 7) ☒ Claim(s) 5, 9-23, 31, and 50 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Mar 28, 2000 is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 20) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I, claims 1-5, 9-55 and 58 in Paper No. 8, filed November 1, 2001 is acknowledged. The traversal is on the ground(s) that the invention of Group II, claims 6-8 and 56-57 drawn to an apparatus for isolating nucleic acid and a method of use cannot be practiced using a materially different process from the invention of claim I, and that the claims of Group II are drawn to an invention which is similarly classified such that a search for Group I would reveal relevant art for the search of Group II. This is not found persuasive because the method of Group I can be practiced without the automated device of Group II. The automated device of Group II may also be used to practice a method which is materially different from the methods of Group I, such as isolation and purification of proteins. The classification of Group I is different from the classification of Group II demonstrating that a materially different search is required for the two groups. Therefore, the arguments are not found convincing.

The requirement is still deemed proper and is therefore made FINAL.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

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Drawings

3. New formal drawings are required in this application because recent changes to the MPEP, section 608.02(c) no longer allow deferral of submission of drawings pursuant to notification. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the Patent and Trademark Office no longer prepares new drawings.

Specification

4. The use of the trademarks RNeasy and Sartolon have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

5. Claims 5, 9-23, 31 and 50 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

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6. Claims 25 and 28 are objected to because of the following informalities: claim 25 recites “release” in line 2 which should read “released” to be grammatically correct. Claim 28 recites “claims 26” at line 1 which should read “claim 26” to be grammatically correct. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-4, 24-30 and 32-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 1 recites “essentially in the same direction as the charging” at lines 5-6. This phrase can be interpreted that the direction is to follow a path back to the point of origin, or in the alternative, can be interpreted as continuing along a path away from the point of origin. As a result the meaning of the claim is unclear.

10. Claims 26 and 28-30 recite the limitation "said immobilization buffer" in line 1. There is insufficient antecedent basis for this limitation in the claim.

11. Claim 27 recites the limitation "the chaotropic agent" in line 1. There is insufficient antecedent basis for this limitation in the claim.

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12. Claims 27, 38 and 45 appear to claim a Markush group without the proper use of the Markush format. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B and C." See *Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 1925).

13. Claims 28-30 recite the limitation "with other salts" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

14. Claim 38 recites the limitation "characterized in that". This term is indefinite since it does not provide the skilled practitioner with a clear definition of the metes and bounds of the claimed subject matter. A characterization may not be complete and thorough in its description of a subject, but a mere recitation of an observation or property pertaining to the subject.

✓15. Claim 41 recites the limitation "the pores" in line 1. There is insufficient antecedent basis for this limitation in the claim.

16. Claim 45 recites the limitation "the chaotropic agent" in line 1. There is insufficient antecedent basis for this limitation in the claim.

17. Claims 46-48 recite the limitation "with other salts" in line 2. There is insufficient antecedent basis for this limitation in the claim.

18. Claim 55 recites the limitation "said membranes" in line 1. There is insufficient antecedent basis for this limitation in the claim.

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Claim Rejections - 35 USC § 102

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20. Claims 1-3, , 24, 26, 28-30, 32-34 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Holmes et al.

Holmes et al. taught (see especially page 110) a process for isolating nucleic acids by charging a hydrophobic polyvinyl chloride filter membrane with nucleic acids, immobilizing the nucleic acids from the top surface of the membrane in an aqueous buffer solution containing a chaotropic agent (3M) in combination with other salts, washing the bound nucleic acids, releasing the nucleic acids from the membrane with an aqueous buffer solution which flowed through the membrane and collecting the released nucleic acids from the bottom of the membrane.

21. Claims 1-3 and 2-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Jakobi et al.

Jakobi et al. taught (see especially page 198, column 2 and page 199, column 1) a process for isolating nucleic acids by charging a hydrophobic glass fiber filter with nucleic acids,

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immobilizing the nucleic acids from the top surface of the membrane in an aqueous buffer solution containing chaotropic agent (4M) in combination with other salts, releasing the nucleic acids from the membrane with water or an aqueous buffer solution which flowed through the membrane and collecting the released nucleic acids from the bottom of the membrane. The chaotropic agent was sodium perchlorate.

22. Claims 1-4, 24-30, 32, 42, 51, 55 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/41810.

WO 96/41810 taught (see especially page 3, lines 3-11, pages 5-7, 13 and the claims) a process for isolating nucleic acids by charging a membrane or fleece with nucleic acids, immobilizing the nucleic acids from the top surface of the membrane or fleece in an aqueous buffer solution containing chaotropic agent (3-6M, pH 5-9) in combination with other salts, releasing the nucleic acids from the membrane or fleece with an aqueous buffer solution which was collected from the top of the membrane or fleece, or was pulled through the membrane by vacuum and collecting the released nucleic acids from the bottom of the membrane. The chaotropic agent was sodium perchlorate, guanidinium hydrochloride, guanidinium salts or sodium iodide. The method can be performed in a multiwell plate.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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23. Claims 1-4, 24 and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,258,531.

US 6,258,531 taught (see especially columns 1-4, 6 and 8-10) a process for isolating nucleic acids by charging a hydrophobic glass fiber fleece with nucleic acids, immobilizing the nucleic acids from the top surface of the fleece, washing the bound nucleic acids with a buffer and releasing the nucleic acids from the top of the fleece with an aqueous buffer solution, or by flowing buffer through the fleece and collecting the released nucleic acids from the bottom of the membrane.

Claim Rejections - 35 USC § 103

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

25. Claims 1-4, 24-30, 32-42, 52-55 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of Holmes et al., Jakobi et al., WO 96/41810, and US 6,258,531 each in view of US 5,004,543.

The claims are drawn to a process for isolating nucleic acids by charging a membrane or fleece with nucleic acids, immobilizing the nucleic acids from the top surface of the membrane or fleece in an aqueous buffer solution containing chaotropic agent (3-6M, pH 5-9) in

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combination with other salts, releasing the nucleic acids from the membrane or fleece with water or an aqueous buffer solution from the top of the membrane or fleece, or which was pulled through the membrane by vacuum and collecting the released nucleic acids from the bottom of the membrane or fleece. The chaotropic agent was sodium perchlorate, guanidinium hydrochloride, guanidinium salts or sodium iodide. The method can be performed in a multiwell plate. The membrane was either hydrophobic or hydrophilic. The membrane was made from either a polymer with polar groups, a hydrophilic polymer, a hydrophobic polymer or a hydrophobized hydrophilic polymer.

Each of Holmes et al., Jakobi et al., WO 96/41810, and US 6,258,531 taught the invention as described above in the rejections under 35 USC 102.

Each of Holmes et al., Jakobi et al., WO 96/41810, and US 6,258,531 did not teach that the membrane was hydrophilic, nor that the membrane was made from either a polymer with polar groups, a hydrophilic polymer or a hydrophobized hydrophilic polymer.

US 5,004,543 taught (see especially the examples and the claims) a hydrophilic membrane for binding nucleic acids. US 5,004,543 taught the improved binding performance of the hydrophilized membranes for binding and purification of nucleic acids.

It would have been obvious to one of ordinary skill in the art at the time of filing the instant application to combine the teachings of each of Holmes et al., Jakobi et al., WO 96/41810, and US 6,258,531 with US 5,004,543 to produce the instant claimed invention

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because US 5,004,543 taught the highly effective use of hydrophilic membranes for binding and purification of nucleic acids.

One of ordinary skill in the art would have been motivated to combine the teachings of each of Holmes et al., Jakobi et al., WO 96/41810, and US 6,258,531 with US 5,004,543 to produce the instant claimed invention because US 5,004,543 taught that the beneficial and desirable hydrophilic membranes provided improved performance for binding and purification of nucleic acids. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of each of Holmes et al., Jakobi et al., WO 96/41810, and US 6,258,531 each in view of US 5,004,543.

The instant specification lists at page 9 a group of equivalent and well known membranes which are hydrophobic, or made of hydrophobic polymers with polar groups, as well as hydrophobized membranes, making obvious the use of any one of the group of hydrophobic or hydrophobized membranes in the claimed instant invention which are also used by the prior art above and are well known to those of ordinary skill in the art for binding of nucleic acids.

26. Claims 1-4, 24-30, 32-49, 52-55 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of Holmes et al., Jakobi et al., WO 96/41810, and US 6,258,531 each in view of US 5,004,543 as applied to claims 1-4, 24-30, 32-42, 52-55 and 58 above, and each further in view of US 5,658,548.

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The claims are drawn to the invention as described above and also where the hydrophobic fleece is a silica gel fleece.

Each of Holmes et al., Jakobi et al., WO 96/41810, and US 6,258,531 each in view of US 5,004,543 taught the invention as described above.

Each of Holmes et al., Jakobi et al., WO 96/41810, and US 6,258,531 each in view of US 5,004,543 did not teach that the hydrophobic fleece is a silica gel fleece.

US 5,658,548 taught (see especially columns 3-7) that silica gel was a “chromatographic grade” of silica (glass) which is characterized as to its porosity, and surface area. Silica gel and glass fibers are used in combination by US 5,658,548 in a method of purification of nucleic acid.

It would have been obvious to one of ordinary skill in the art at the time of filing the instant application to combine the teachings of each of Holmes et al., Jakobi et al., WO 96/41810, US 6,258,531 and US 5,004,543 with US 5,658,548 to produce the instant claimed invention because US 5,658,548 taught that silica gel is a well characterized form of silica (glass) which is used routinely in the binding and isolation of nucleic acids.

One of ordinary skill in the art would have been motivated to combine the teachings of each of Holmes et al., Jakobi et al., WO 96/41810, US 6,258,531 and US 5,004,543 with US 5,658,548 to produce the instant claimed invention because US 5,658,548 taught that silica gel is a chromatographic grade of silica (glass), and that it was beneficial and desirable to use in a method of binding and eluting nucleic acids. Silica gel fleece is a chromatographic grade of glass fiber fleece which is commercially available and well known to those of ordinary skill in

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the art. Glass fiber fleece is taught by US 6,358,531 as one form of hydrophobic surface useful for the binding and isolation of nucleic acids. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of each of Holmes et al., Jakobi et al., WO 96/41810, and US 6,258,531 each in view of US 5,004,543 and further in view of US 5,658,548.

Conclusion

27. Certain papers related to this application are *welcomed* to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Friday from 8:30 AM to 5:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Zeta Adams, whose telephone number is (703) 305-3291.

William Sandals, Ph.D.
Examiner
March 11, 2002